אוגוסט 2025

DUPIXENT 300mg solution for injection

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חומר פעיל: dupilumab 300mg/2ml (150 mg/ml)

חומר פעיל: dupilumab 200mg/1.14ml (175 mg/ml)

ההתוויות המאושרות:

Atopic Dermatitis

DUPIXENT is indicated for the treatment of adult and pediatric patients aged 6 months and older with moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. DUPIXENT can be used with or without topical corticosteroids.

Asthma

DUPIXENT is indicated as an add-on maintenance treatment of adult and pediatric patients aged 6 years and older with moderate-to-severe asthma characterized by an eosinophilic phenotype or with oral corticosteroid dependent asthma.

Limitation of Use

DUPIXENT is not indicated for the relief of acute bronchospasm or status asthmaticus.

Chronic Rhinosinusitis with Nasal Polyposis

DUPIXENT 300mg is indicated as an add-on maintenance treatment in adult patients with inadequately controlled chronic rhinosinusitis with nasal polyposis (CRSwNP).

Eosinophilic Esophagitis

DUPIXENT is indicated for the treatment of adult and pediatric patients aged 1 year and older, weighing at least 15 kg, with eosinophilic esophagitis (EoE).

Prurigo Nodularis

DUPIXENT 300mg is indicated for the treatment of adults with moderate-to-severe prurigo nodularis (PN) who are candidates for systemic therapy.

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Chronic Obstructive Pulmonary Disease

DUPIXENT is indicated as an add-on maintenance treatment of adult patients with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.

Limitations of Use:

DUPIXENT is not indicated for the relief of acute bronchospasm.

חברת סאנופי מבקשת להודיע על עדכון העלונים לרופא ולצרכן.

העדכונים העיקריים הינם:

בעלון לרופא:

5 WARNINGS AND PRECAUTIONS

5.1 Hypersensitivity

Hypersensitivity reactions, including anaphylaxis, acute generalized exanthematous pustulosis (AGEP), serum sickness or serum sickness-like reactions, angioedema, generalized urticaria, rash, erythema nodosum and erythema multiforme have been reported. If a clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue DUPIXENT *[see Adverse Reactions (6.1, 6.2, and Clinical Pharmacology (10.4)]*.

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6. ADVERSE REACTIONS

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6.1 Clinical Trials Experience

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Atopic Dermatitis

Adults with Atopic Dermatitis

Three randomized, double-blind, placebo-controlled, multicenter trials (SOLO 1, SOLO 2, and CHRONOS) and one dose-ranging trial (AD-1021) evaluated the safety of DUPIXENT in subjects with moderate-to-severe AD *[see Clinical Studies (12)]*. In terms of co-morbid conditions, 48% of the subjects had asthma, 49% had allergic rhinitis, 37% had food allergy, and 27% had allergic conjunctivitis. In these 4 trials, 1472 subjects

were treated with subcutaneous injections of DUPIXENT, with or without concomitant topical corticosteroids (TCS).

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Prurigo Nodularis

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Subjects with co-morbid conditions included 43% of subjects with a history of atopy (defined as having a medical history of AD, allergic rhinitis/rhino conjunctivitis, asthma, or food allergy), 8% of subjects with a history of hypothyroidism and 9% of subjects with a history of diabetes mellitus type 2.

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Hypersensitivity Reactions

Hypersensitivity reactions were reported in <1% of DUPIXENT-treated subjects. These included anaphylaxis, AGEP, serum sickness or serum sickness-like reactions, generalized urticaria, rash, erythema nodosum and erythema multiforme *[see Contraindications (4), and Clinical Pharmacology (10.4)].*

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7. USE IN SPECIFIC POPULATIONS

7.1 Pregnancy

Risk Summary

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Fetal/Neonatal Adverse Reactions

Transport of endogenous IgG antibodies across the placenta increases as pregnancy progresses, and peaks during the third trimester. Therefore, DUPIXENT may be present in infants exposed *in utero*. The potential clinical impact of dupilumab exposure in infants exposed *in utero* should be considered.

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10. CLINICAL PHARMACOLOGY

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10.4 Immunogenicity

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The anti-drug antibody (ADA) and neutralizing antibody (NAb) incidence rates in subjects treated with DUPIXENT are presented in Table 12.

Table 12: Anti-drug Antibody and Neutralizing Antibody Incidence in Subjects Treated with DUPIXENT

Indication and Population	Dose and Duration of Treatment	Anti-drug Antibody (ADA)		Neutralizing Antibody NAb [c]
		Treatment-Emergent ADA[a]	Persistent ADA[b]	
Atopic Dermatitis				
Adult	300 mg Q2W for 52 weeks	6/105 (6%)	2/105 (2%)	1/6 (17%)
12 to 17 years of age	300 mg or 200 mg Q2W for 16 weeks	13/81 (16%)	2/81 (3%)	4/13 (31%)
6 to 11 years of age	200 mg Q2W or 300 mg Q4W for 16 weeks	3/171 (2%)	0/171 (0%)	1/3 (33%)
6 months to 5 years of age	200 mg Q4W, or 300 mg Q4W for 16 weeks	1/74 (1%)	0/74 (0%)	0/1 (0%)
Asthma				
Adult and 12 years of age or older	300 mg Q2W for 52 weeks	32/626 (5%)	13/626 (2%)	14/32 (44%)
	200 mg Q2W for 52 weeks	58/625 (9%)	26/625 (4%)	27/58 (47%)
6 to 11 years of age	100 mg Q2W or 200 mg Q2W up to 52 weeks	17/269 (6%)	9/269 (3%)	6/17 (35%)
Chronic Rhinosinusitis with Nasal Polyps				
Adult	300 mg Q2W for 52 weeks	8/148 (5%)	3/148 (2%)	5/8 (63%)
Eosinophilic Esophagitis				
Adult and 12 years of age or older	300 mg QW for 52 weeks	1/108 (1%)	0/108 (0%)	0/1 (0%)

1 to 11 years of age	200 mg Q2W or 300 mg Q2W for 52 weeks [e]	1/37 (3%)	0/37 (0%)	0/1 (0%) [d]
Prurigo Nodularis				
Adult	300 mg Q2W for 24 weeks	11/143 (8%)	2/143 (1%)	4/11 (36%)
Chronic Obstructive Pulmonary Disease				
Adult	300 mg Q2W for 52 weeks	77/922 (8%)	24/922 (3%)	28/77 (36%)

[a] Treatment-emergent ADA: A negative result or missing result at baseline with at least 1 positive post-baseline result in the ADA assay.
[b] Persistent ADA: A treatment-emergent ADA positive response with 2 or more consecutive ADA positive samples separated by a greater than 12-week period (>84 days), with no ADA negative result in between.
[c] Neutralizing potential is assessed only for ADA-positive samples. The NAb incidence is reported as a percentage of subjects with treatment emergent ADA.
[d] One subject 1 to 11 years of age with EoE with pre-existing immunoreactivity that was positive for neutralizing antibodies was excluded from the NAb positive subjects.
[e] Immunogenicity was reported on pooled data for pediatric subjects 1 to 11 years of age with EoE receiving SC dupilumab 100 mg Q2W (in subjects weighing ≥5 kg to <15kg), 200 mg Q2W (in subjects weighing ≥15 kg to <30 kg), 300 mg Q2W (in subjects weighing ≥30 kg to <60 kg), and 300 mg QW (in subjects weighing ≥60 kg).

Two adult subjects with AD who experienced high titer antibody responses developed serum sickness or serum sickness-like reactions during DUPIXENT therapy [see *Warnings and Precautions (5.1)*].

The antibody titers detected in subjects who received DUPIXENT were mostly low. In subjects who received DUPIXENT, development of high titer antibodies to DUPIXENT was associated with lower serum dupilumab concentrations [see *Clinical Pharmacology (12.3)*].

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12. CLINICAL STUDIES

12.1 Atopic Dermatitis

Adults with Atopic Dermatitis

Three randomized, double-blind, placebo-controlled trials (SOLO 1 , SOLO 2, and CHRONOS) enrolled a total of 2119 adult subjects 18 years of age and older with moderate-to-severe AD not adequately controlled by topical medication(s). Disease severity was defined by an Investigator's Global Assessment (IGA) score ≥3 in the overall assessment of AD lesions on a severity scale of 0 to 4, an Eczema Area and Severity Index (EASI) score ≥16 on a scale of 0 to 72, and a minimum body surface area involvement of ≥10%. At baseline, the mean age of subjects was 38 years; 59% of subjects were male, 67% were White, 24% were Asian, and 6% were Black; 52% of subjects had a baseline IGA score of 3 (moderate AD), and 48% of subjects had a baseline IGA of 4 (severe AD). The baseline mean EASI score was 33 and the baseline weekly averaged Peak Pruritus Numeric Rating Scale (NRS) was 7 on a scale of 0-10.

בעלונים לצרכן (עבור שני המינונים, באריזת מזרקים ובאריזת עטי הזרקה):

4. תופעות לוואי

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דופיקסנט יכולה לגרום לתופעות לוואי חמורות כולל:

- **תגובות אלרגיות. דופיקסנט יכולה לגרום לתגובות אלרגיות, כולל תגובות בעור, שיכולות לפעמים להיות חמורות.**
  הפסק את השימוש בדופיקסנט ופנה מייד לרופא שלך או למוקד חירום, אם מופיעים אחד או יותר מהסימנים או התסמינים הבאים:
  בעיות בנשימה או צפצופים, נפיחות בפנים, בשפתיים, בפה, בלשון או בגרון, עילפון, סחרחורת, תחושת סחרור, דופק מהיר, חום, הרגשת חולי כללית, בלוטות לימפה נפוחות, כאבי מפרקים, חרלת, גירוד, בחילה או הקאה, התכווציות באזור הקיבה.
  פריחה עורית, כולל פריחה שנראית כמו מטרה, בליטות אדומות או כחולות כואבות מתחת לעור, או נקודות אדומות מלאות מוגלה על העור.
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תופעות הלוואי השכיחות ביותר של דופיקסנט:

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- בעיות בעיניים, כולל דלקת בעיניים ובעפעפיים, אדמומיות, נפיחות, גירוד, זיהום בעין, יובש בעין וראייה מטושטשת
- .....
- בעיות בקיבה (דלקת בקיבה)
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העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים על ידי פנייה לבעל הרישום - סאנופי ישראל בע"מ, Greenwork Park, מתחם העסקים בקיבוץ יקום, בניין E (קומה 1), 6097600, יקום או בטלפון: 09-8633081.

להלן הקישור לאתר משרד הבריאות: https://israeldrugs.health.gov.il/#!/byDrug

בברכה,

חברת סאנופי ישראל בע"מ